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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
09/559,452	04/27/2000	Kevin D. McIntosh	P-9056.00	1849
27581	7590	11/02/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/559,452

Applicant(s)

MCINTOSH ET AL.

Examiner

Patricia M Bianco

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/3/04 & 7/19/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-13, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14-22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Final Rejection.

DETAILED ACTION

Response to Amendment

Claims 1, 4, 10, 17 & 25 were amended. Claims 1-25 remain pending. Claims 11-13, 23 & 24 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 1, 10, 14-17 & 19-22 claim "**a channel**" as part of the claimed invention. Nowhere in the detailed description and drawings is a channel taught or shown in relation to the fluid oxygenating apparatus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-10, & 14-22 are finally rejected under 35 U.S.C. 102(b) as being anticipated by White et al. (5,762,869). White et al. (hereafter White) disclose a method and apparatus for oxygenating blood wherein the apparatus includes a blood

Art Unit: 3762

oxygenator and heat exchanger (36). The oxygenator has a housing (10) defining a chamber within wall (22). A core (126) within the housing chamber may have a hollow fiber bundle (175) around the core. The apparatus has a gas/bubble release port (90), blood inlet (35), blood outlet (76), gas inlet (66) and gas outlet (68). The apparatus has a lid or cap portion (26) that is dome shaped. It is attached via a flange to the housing cylindrical seat (30) portion. With respect to claim 3, White discloses that the cap is sealed after attached, therefore it is, at some point, a separate member that is attached. The fibers are secured via a first and a second potting element (178/180) at the ends of the fibers. With respect to claims 14-16, the limitations are met since the apparatus of White has a conical tapering or funneling outlet or channel that extends into the outlet and allows for the exit of gas bubbles through the outlet port 90 (col. 8, lines 20-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 3762

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. ('869). White et al. disclose the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the bubble release port is positioned between the fiber bundle and a top end of the manifold. White teaches that the auxiliary port/gas vent 90 (i.e. bubble release) is located between the hollow fiber bundle and the bottom of the manifold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the housing with the bubble release port is positioned between the fiber bundle and a top end of the manifold, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claims 5 and 6 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. ('869) in view of Winters et al. (5,338,770). White et al. disclose the invention substantially as claimed, see rejection supra, however, fails to disclose specifically a biocompatible coating on the fibers. Winters et al. disclose a siloxane coating for gas permeable biomedical devices, such as hollow fibers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of White to use a hollow fiber with a coating as taught by

Art Unit: 3762

Winters, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 5/03/04 & 7/19/04 have been fully considered but they are not persuasive. Applicant argues that White et al. do not teach of a channel through the core having an inlet end and an outlet end in fluid communication with the fluid inlet and outlet end of the housing & a bubble release port in communication with the outlet end of the channel (with respect to claim 1), a heat exchanger operatively connected to the channel (with respect to claim 10), the step of flowing debubbled fluid through the plurality of fibers (with respect to claim 18), and a manifold in the core having an inlet (with respect to claim 25).

In response to applicants' argument that White does not teach of a channel that is through the core having an inlet end and an outlet end in fluid communication with the fluid inlet and outlet end of the housing & a bubble release port in communication with the outlet end of the channel (with respect to claim 1) and a heat exchanger operatively connected to the channel (with respect to claim 10), the examiner disagrees. White teaches of a channel (192) that is within the core of the housing and has inlet and outlet portions in communication with the inlet and outlet (35 and 76 respectively), and it is further in communication with the heat exchanger via inlet 35 since blood moves through said heat exchanger.

In response to applicants' argument that White does not teach that the fluid passed through the fibers is a debubbled fluid as required by claim 18, the examiner respectfully disagrees. In col. 5, lines 20-25, White teaches that the blood flowing through the housing, and thereby through the fibers, is free of entrained gas. Therefore, it is debubbled fluid.

In response to applicants' argument that the references fail to show certain features of applicant's invention, it is noted that a features upon which applicant relies (i.e., manifold in the core having an inlet, with respect to claim 25) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 25 does not set forth the manifold having an inlet.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 3762

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.

October 30th, 2004

Patricia M Bianco
Primary Examiner
Art Unit 3762


PATRICIA BIANCO
PRIMARY EXAMINER